

### **REMARKS**

Claims 1, 3-5, 11-13, 22-23, 25, and 38-43 are currently pending. Claims 1, 3, 4, 12, 13, 22, 25, and 38-40 are rejected under 35 U.S.C. §102(b), and claims 5, 11, 23, and 41-43 are rejected under 35 U.S.C. §112. Applicants respectfully traverse the rejections.

### **Rejections Under 35 U.S.C. §102**

First, the Examiner argues that claims 1, 3, 4, 12, 13, 25, and 40 are invalid under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,620,867 (“Kiefer”). The Examiner argues that Kiefer discloses a peptide comprising the amino acid sequence of SEQ ID NO: 1, and the claims do not require a peptide that increases the rate or degree of osteogenesis or calcification, so Kiefer anticipates the claims as written. Applicants respectfully disagree with the Examiner’s assessment. Claims 1, 3, 4, 12, 13, 25, and 40 are drawn to a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof, wherein said *peptide or fragment increases the degree or rate of osteogenesis or calcification*, for example when administered with a BMP.

For a prior art reference to anticipate the claimed invention, the prior art reference must contain every element of the claimed invention. *See Zenith Electronics v. PDI Communications Systems*, 522 F.3d 1348, 1363 (Fed. Cir. 2008). As Dr. Murray explains in her attached declaration, Kiefer discloses spp24, and spp24 *inhibits bone formation*. Murray Declaration, at ¶¶ 5-7; 10-13. Thus, the peptides that Kiefer discloses *are not pro-osteogenic*. *Id.* Moreover, Kiefer *does not disclose any fragments* of spp24 that are pro-osteogenic. *Id.* Because the claims are drawn to a peptide comprising BBP, which is *pro-osteogenic*, and Kiefer does not disclose any peptide fragments of spp24 that are pro-osteogenic, Kiefer does not disclose each and every limitation of the claimed invention.

Moreover, to the extent that the Examiner is arguing that Kiefer inherently anticipates the claimed invention, Applicants respectfully disagree. Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate...if the missing element is *necessarily* present in the thing described in the reference, and *that it would be so recognized by persons of ordinary skill.*” *See Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2002)(emphasis added). Here, the Examiner presents no evidence that one skilled in the art reading Kiefer would understand this reference to teach the claimed BBP peptide, or a fragment thereof, that *increases the degree or rate of osteogenesis or*

*calcification*. In actuality, Kiefer provides *absolutely no data or other evidence* to support the disclosure that the disclosed spp24 peptides are pro-oestrogenic. Murray Dec., at ¶¶ 5-9. Thus, Applicants respectfully submit that Kiefer does not disclose, inherently or otherwise, a peptide comprising BBP, or a fragment thereof, that increases the degree or rate of osteogenesis or calcification.

The Examiner also argues that claims 1, 3, 4, 12, 13, 22, 25, and 38-40 are invalid under 35 U.S.C. §102(b) as anticipated by WO 96/21006 ("Price"). The Examiner argues that Price discloses a peptide comprising the amino acid sequence of SEQ ID NO: 1, and the claims do not require a peptide that increases the rate or degree of osteogenesis or calcification, so Price anticipates the claims as written. Applicants respectfully disagree with the Examiner's assessment. As explained above, claims 1, 3, 4, 12, 13, 22, 25, and 38-40 are drawn to a peptide comprising the amino acid sequence of SEQ ID No: 1 or a fragment thereof, wherein said *peptide or fragment increases the degree or rate of osteogenesis or calcification*, for example when administered with a BMP.

Price discloses spp24, which *inhibits bone formation*. Murray Declaration, at ¶¶ 5-6; 10-13. Moreover, Price does not disclose a fragment of spp24 that *increases the degree or rate of osteogenesis or calcification*. *Id.* Because the claims, as amended, *do require* a peptide comprising BBP, or a fragment thereof, that *increases the degree or rate of osteogenesis or calcification*, and Price does not disclose a fragment of spp24 that induces bone formation, Applicants respectfully submit that Price does not disclose, inherently or otherwise, all of the elements of the claimed invention.

### **Rejections Under 35 U.S.C. §112**

The Examiner argues that claims 5, 11, 23, and 41-43 are invalid under 35 U.S.C. § 112 as not enabled because the claims encompass spp24, which does not induce bone formation. Applicants respectfully disagree with the Examiner's arguments. As explained above, the claims do not encompass spp24. Rather, the claims are drawn to a peptide or fragment that *increases the degree or rate of oestogenesis or calcification* when administered with, for example, a BMP. Because as the Examiner acknowledges, spp24 *does not increase the degree or rate of osteogenesis or calcification*, for example when administered with a BMP, spp24 is not

*encompassed within the scope of* claims 5, 11, 23, and 41-43. Thus, Applicants respectfully submit that claims 5, 11, 23, and 41-43 are enabled.

### **CONCLUSION**

In light of the foregoing reasons, Applicants respectfully submit that all of the claims in the application are in allowable form, and the application is now in condition for allowance. Applicant requests the Patent Office to indicate all claims as allowable and to pass the application to issue.

The Commissioner is authorized to charge any additional fees or credit any overpayments associated with this Amendment to Deposit Account 13-0206. Applicants further invite the Examiner to contact the undersigned representative at the telephone number below to discuss any matters pertaining to the present Application. The Examiner is requested to contact the undersigned if the Examiner has any questions concerning this Response, or if it will expedite the progress of this application.

Respectfully submitted,

Dated: December 30, 2011

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